

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION This document relates to: WAVE 2 (Cases Identified in Exhibit A to Ethicon's Motion to Exclude)	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE
SUZANNE PARISIAN, M.D., RELATING TO THE TVT-SECUR DEVICE
[WAVE 2]**

Defendants Ethicon, Inc. and Johnson & Johnson submit this Reply in Support of Defendants' Motion to Exclude Suzanne Parisian, M.D., Relating to the TVT-Secur Device. [ECF No. 2387 (Mot.); ECF No. 2388 (Mem. in Support)]. For the reasons stated below and in Defendants' opening motion and memorandum, Dr. Parisian's testimony should be excluded as to the three applicable cases identified in Exhibit A to Ethicon's motion.

I. Plaintiffs' Opposition overlooks citations in Ethicon's motion and memorandum regarding Dr. Parisian's previous state court testimony.

Plaintiff's Memorandum in Opposition [ECF No. 2542 ("Pl. Opp.")] criticizes Ethicon for "conveniently fail[ing] to mention that Dr. Parisian has been allowed to testify in TVM state courts [sic] actions" Pl. Opp. at 4. This is unjustified. Not only did Ethicon address this in its Reply in Wave I, *see* ECF No. 2229 at 10, 13-14, but also included it (with reference to the exhibit from Plaintiff's prior briefing) in its opening memorandum here in Wave 2. *See* Def. Mem., ECF No. 2388, at 4, 13.

What is more, the state court testimony actually supports Ethicon's arguments for exclusion. First, the judge in the state court case acknowledged that he had "some indication from counsel that this witness tends to go far afield. And we need to make sure and corral this witness that instead of expressing generalized opinions be based again on her expertise with FDA approval processes and federal regulations." *See* Pl. Opp. at Exh. A, at 21:7-12. Second, it did not apply the same standards as this Court with respect the scope of expert testimony on federal regulations and compliance with FDA processes. *Compare id.*, with Defs.' Mot. at 11-14. Third, that court acknowledged that Dr. Parisian should be limited with regard to the labeling as to "whether or not that is information that should have been provided to the physicians." Pl. Opp. at Exh. A at 21:13-20.

II. Plaintiffs fail to specify the topics upon which Dr. Parisian will not testify.

Plaintiffs also challenge Ethicon for moving to exclude "opinions that Dr. Parisian overtly states she will not offer." Pl. Opp. at 4 (emphasis in original). Plaintiffs, however, do not specify or confirm those topics upon which Dr. Parisian will not opine. Ethicon—and the Court—are left to guess what the parameters of her intended testimony will be. Given that Dr. Parisian devotes many pages of her 113-page expert report to these issues, Plaintiffs' vague concession does not provide sufficient assurance that Dr. Parisian will not delve into these plainly improper matters at trial. *See, e.g., In re Trasylol Prods. Liab. Litig.*, 709 F.Supp.2d 1323, 1351 (S.D. Fla. 2010); *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp.2d 420, 467 (E.D. N.Y. 2011) ("The Court finds that the Plaintiffs' assertion that Dr. Parisian does not offer such opinions to be disingenuous.").

III. Dr. Parisian claims that she will *not* testify on medical causation—but Plaintiffs nevertheless argue that she is qualified to do so and offers a reliable methodology. She is not and does not.

There is no better example of the problems in limiting Dr. Parisian’s anticipated testimony than with medical causation and related scientific testimony (e.g., product development, risks, design, testing, manufacturing, studies, or the standard of care for treating physicians).

On this issue, Plaintiffs’ Opposition is inherently contradictory. On one hand, Plaintiffs ignore that Dr. Parisian stated in her expert report, *and* testified under oath, that she would not offer any general or specific causation opinions. But on the other hand, Plaintiffs’ Opposition devotes several pages’ worth of argument to claim that Dr. Parisian is qualified and her opinions reliable. *Compare* Defs.’ Mem. at 4-10, *with* Pl. Opp. at 5-6.¹

If there were any question about Dr. Parisian’s intent to opine on scientific testimony (including research, product or study design, medical causation, risks, etc.), it is confirmed by review of her proffered opinions in her expert report.

TVT-S
OPINION #1 - ETHICON's 510(K) FAILED TO ADEQUATELY DESCRIBE A FULL AND ACCURATE DISCLOSURE OF THE MANY SIGNIFICANT DIFFERENCES BETWEEN TVT-SECUR (A NEW SIS MINI TAPE) AND THE TVT AND TVT-O SYSTEM PREDICATES ORIGINALLY CITED BY ETHICON. ETHICON FAILED TO DESCRIBE RISKS ASSOCIATED WITH THE DEVICE PRIOR TO CLEARANCE. DESPITE THE FORESEEABLE AND UNANSWERED RISKS REMAINING FOR IMPLANTING WOMEN WITH A NEW MINI SLING, ETHICON WAS ABLE TO REFERENCE GYNE IDEAS' MINI TAPE DEVICE AS A PREDICATE AND AVOID OBTAINING CLINICAL DATA PRIOR TO 510(K) CLEARANCE.

¹ Plaintiff’s Opposition is not responsive to Ethicon’s motion regarding qualifications. Section I of the opposition suggests that Ethicon has moved to exclude Dr. Parisian as unqualified across the board. That is not an accurate portrayal of what Ethicon has advanced, and Plaintiffs’ attempt to globally address Dr. Parisian’s “qualifications” does not respond to the distinct areas where she seeks to offer opinions beyond her background and experience.

OPINION #2 - ETHICON KNEW THERE WERE NEW RISKS FOR SIS MINI SLING WHEN COMPARED TO TVT AND TVT-O SYSTEMS BASED ON CHANGES MADE TO HELP REDUCE COSTS. HOWEVER, ETHICON CHOSE NOT TO STUDY THE IMPACT OF THOSE CHANGES FOR PATIENT SAFETY. ETHICON DID NOT UPDATE ITS TVT-SECUR IFU TO ADEQUATELY WARN OF INCREASED RISKS FOR PREMATURE FAILURE, CHRONIC PAIN, DYSPAREUNIA, MESH EXTRUSION AND EROSION, CHRONICITY AND WORSENING OF SYMPTOMS, DIFFICULTIES WITH MESH REMOVAL, DIFFICULTIES WITH INSERTER FUNCTION AND PATIENT NEED FOR ADDITIONAL SURGERY.

OPINION #3 - ETHICON, DESPITE HAVING MADE SPECIFIC ASSURANCES TO ITS OWN MEDICAL INVESTIGATORS THAT CERTAIN ADDITIONAL SAFETY STUDIES WOULD BE PERFORMED DID NOT LIVE UP TO THAT AGREEMENT.

OPINION #4 - ETHICON'S MARKETING FOR TVT-S TARGETED SURGEONS WITHOUT REGARD AS TO PELVIC SURGERY EXPERIENCE, MINIMIZING DIFFICULTIES FOR PLACEMENT OF THE MINI SLING, INACCURATELY CALLING IT 'LESS INVASIVE' WHILE KNOWING THE PROCEDURE HAD A SIGNIFICANT SURGEON LEARNING CURVE, THE 'U' APPROACH WAS HARDER TO PERFORM THAN THE 'HAMMOCK', DIFFICULTIES WERE REPORTED WITHDRAWING THE INSERTER WITHOUT DISPLACING THE MINI SLING. ETHICON SELECTIVELY PROVIDED SOME SURGEONS WITH UPDATED INSTRUCTIONS AND SURGICAL TIPS WHILE ETHICON FAILED TO ADEQUATELY UPDATE ITS OWN LABEL, IFU AND MARKETING AND SALES FORCE TO WARN 'ALL' SURGEONS EQUALLY OF TVT-SECUR INCREASED RISKS COMPARED TO OTHER TREATMENT OPTIONS FOR SUI. FINALLY, ETHICON FAILED TO WARN SURGEONS ABOUT PATIENT RISKS FOR MESH EXTRUSION, EROSION, CHRONIC PAIN, WORSENING OF SYMPTOMS, DYSPAREUNIA AND NEED FOR ADDITIONAL SURGERY.

OPINION #5 - DESPITE ETHICON'S KNOWLEDGE OF POST-MARKET DIFFICULTIES FOR THE TVT-S SYSTEM, INCLUDING HIGH FAILURE RATE, BLADDER PERFORATIONS, COMPLAINTS FROM ITS OWN TRAINED KEY OPINION LEADERS (KOL), AND THAT EUROPEAN SURGEONS HAD STOPPED PERFORMING TVT-SECUR IN 2007 BASED ON UNACCEPTABLE RISKS, ETHICON CONTINUED TO MARKET TVT-SECUR IN THE UNITED STATES WITHOUT NOTIFYING SURGEONS OR PATIENTS ABOUT THE INCREASED RISKS. ETHICON DID NOT VOLUNTARILY CONDUCT POST-MARKET SURVEILLANCE STUDIES INCLUDING THE 522 STUDY IN ORDER TO UPDATE ITS AMERICAN LABEL, PHYSICIANS AND WOMEN WITH ACCURATE RISK INFORMATION.

OPINION #6 - BASED ON ETHICON'S MISREPRESENTATIONS TO ITS SALES FORCE AND PHYSICIANS AS WELL AS THE FDA, INCLUDING ITS FAILURE TO CONSIDER AND DISCLOSE THAT THE MOST EXPERIENCED SURGEONS WITH TVT-S EXPERIENCED DIFFICULTIES AND PREMATURE FAILURES WITH THE DEVICE, IMPLANTING SURGEONS WOULD NOT HAVE BEEN ABLE TO PROVIDE PATIENTS

WITH AN ADEQUATE INFORMED CONSENT BASED ON KNOWLEDGE OF THE RISKS OF THE TVT-S PRODUCT AS A SIS MINI SLING FOR SUI

OPINION #7 - SURGEONS RELIED ON THE KNOWLEDGE, SKILL AND EXPERIENCE OF ETHICON AS A MAJOR UNITED STATES MEDICAL DEVICE MANUFACTURER TO ADEQUATELY INFORM THEM OF THE RISKS FOR THE TVT-S AND PROVIDE PHYSICIANS WITH SAFE AND EFFECTIVE PRODUCTS TO PERMANENTLY IMPLANT IN WOMEN.

Plaintiffs assert that Dr. Parisian’s opinions are “regulatory opinions,” but even a cursory review of the 13 opinions in Dr. Parisian’s TVT-S report reveals that each opinion contains a far-reaching panoply of issues—not just “regulatory” matters. *See* Exh. B to Defs.’ Mot. (TVT-S Expert Report). These proffered opinions show the fallacy of Plaintiffs’ contention: that Ethicon is arguing to exclude “illusory opinions that Dr. Parisian does not offer or seek to present at trial.” Pl. Opp. at 5. Far from it, Ethicon has read what Dr. Parisian has put in her expert reports and believes that to be an accurate representation of what she intends to offer.

Simply put, Plaintiffs cannot have it both ways. Either Dr. Parisian intends to opine on this type of highly scientific testimony or she does not. It certainly appears—despite Dr. Parisian’s statements and testimony to the contrary—that she intends to delve deeply into these topics. If Dr. Parisian does attempt to offer medical or scientific testimony, the Court should exclude such any opinions because she is not qualified and her opinions are not founded on reliable methodology. As stated in *Stambolian v. Novartis Pharms. Corp.*, 2013 WL 6345566, *9 (C.D. Cal. Dec. 6, 2013): “Dr. Parisian is not permitted to testify to things outside of her expertise. This includes testimony that may be couched as regulatory causation but in actuality speaks to medical causation. Dr. Parisian is not qualified to testify to the causal connection” between the products and alleged injury.

Moreover, Plaintiffs' Opposition does not address the relatively recent decision in *Rheinfrank v. Abbott Labs.* There, the district court excluded Dr. Parisian from testifying about "matters outside the scope of her expertise," including her opinion that certain birth defect risks were "knowable" to Abbott; the court ruled "she is not qualified to opine that certain risks of Depakote would have been known by 2003 had Abbott conducted research sooner or in a different manner." See *Rheinfrank v. Abbott Labs.*, Case No. 1:13-cv-144-SJD (S.D. Ohio), Order Ruling on *Daubert* Motions (ECF No. 298), at 16-17, attached as Exh. D to Def. Mot. [ECF No. 2387].

Plaintiffs also claim that Ethicon only challenges Dr. Parisian's qualifications because she has not treated a patient in 30 years. Pl. Opp. at 5-6. This contention is both incomplete and inaccurate. It is incomplete because—although omitted by Plaintiffs in the select quote in their opposition—Ethicon explained that Dr. Parisian has not treated a patient in 30 years, "*long before the TVT-Secur was placed on the market.*" Compare Pl. Opp. at 5, with Def. Mem. at 4 (emphasis added). Plaintiffs thus ignore a critical fact and timeframe with respect to Dr. Parisian's prior background vis-à-vis the only product in issue.

Plaintiffs' argument is also inaccurate: even a cursory review of Ethicon's brief reveals that Dr. Parisian's lack of clinical experience is only one of many shortcomings that render her unqualified here. Plaintiffs do not, and cannot, dispute the following facts regarding Dr. Parisian's qualifications and lack of reliable methodology in arriving at her opinions:

- She has never performed surgery to treat pelvic organ prolapse;
- She has never participated in any animal or cadaver studies regarding any mesh;
- She has never designed mesh;
- She has never done any biomechanical testing or lab work of mesh;

- She has never done any lab work regarding mesh;
- She has never tested a polypropylene or mesh explant;
- She has never inspected or even looked at a mesh explant of any kind under a microscope, and she has never seen the product implanted, watched a video, held the device, or been in the same room as the product;
- She had never heard of the products until asked to look at it for litigation;
- She has no idea how many of the devices have been implanted in the United States or the world;
- She never worked on any mesh products during her four-year position at FDA;
- She has never spoken with a physician who has implanted the device or read the deposition of any physician who has implanted the device;
- She does not know if there is medical literature that implanting physicians should read;
- She does not know what the medical community knew at pertinent times regarding the product in question: for instance, she does not know whether the medical community knew of chronic dyspareunia, chronic pain, vaginal scarring, urinary problems, organ/nerve damage, bleeding/wound complications, inflammation, fistula formation, neuromuscular problems, need for additional surgeries, or risks of erosion, exposure, extrusion, contraction, or shrinkage.

See Defs.' Mem. at 6-10, 14-20.

Plaintiffs repeatedly resort to Dr. Parisian's stint at the FDA to make her an expert in *all* things. She is not. *See, e.g., In re Trasyol Prods. Liab. Litig.*, 709 F. Supp.2d 1323, 1337 (S.D. Fla. 2010) ("Dr. Parisian is neither a causation expert nor an epidemiologist," and "[w]hile Dr. Parisian's Report contains many opinions on the findings of scientific studies related to Trasyol and the association of Trasyol with various health risks, the Report alone did not allow me to conclude with certainty whether Dr. Parisian's experience at the FDA qualifies her to make such opinions . . ."). Because Dr. Parisian is unqualified, and her opinions are not based on a reliable methodology, any opinions on medical or scientific testimony should be excluded.

IV. Plaintiffs first concede, then try to salvage, Dr. Parisian’s “state of mind” opinions, but they are inadmissible.

Like the arguments above, Plaintiffs’ Opposition both giveth and taketh away regarding Dr. Parisian’s regulatory opinions and “state of mind” testimony. The opposition states that “Plaintiffs will comply with this Court’s prior rulings and will not elicit testimony from Dr. Parisian on Defendants’ state of mind, motive, or intent.” Pl. Opp. at 7. Almost in the same breath, however, the opposition delves into why (in Plaintiffs’ estimation) Dr. Parisian’s testimony will not be subject to exclusion after all, claiming that this testimony is “not necessarily” “state of mind” testimony. *Id.*

Again, review of Dr. Parisian’s expert opinions—as she herself drafted them—belie the notion that she will “not necessarily” drift into inadmissible territory. Her opinions are instead replete with commentary on Ethicon’s “corporate willingness,” lack of “commitment to conduct[ing] robust ... surveillance,” or management decisions to discontinue sales rather than obtain information about the product for doctors and patients, and failure to adhere to the “company’s code of conduct to conduct business with integrity and do the right thing” (emphasis added):

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SECUR IFU TO ADEQUATELY WARN OF INCREASED RISKS FOR PREMATURE FAILURE, CHRONIC PAIN, DYSPAREUNIA, MESH EXTRUSION AND EROSION, CHRONICITY AND WORSENING OF SYMPTOMS, DIFFICULTIES WITH MESH REMOVAL, DIFFICULTIES WITH MESH REMOVAL, DIFFICULTIES WITH INSERTER FUNCTION AND PATIENT NEED FOR ADDITIONAL SURGERY.

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Dr. Parisian clearly intends to proclaim her beliefs about Ethicon's knowledge, its state of mind, and whether it acted reasonably. This is impermissible expert opinion. As one federal court has observed, "[m]yriad other courts have observed and excluded this type of testimony in Dr. Parisian's reports in the past." *See* Defs. Mem. at 10-11 (collecting cases; citation from *Lopez v. I-Flow Inc.*, 2011 WL 1897548, *11 (D. Ariz. Jan. 26, 2011)). *See also Rheinfrank, supra* at 17 ("Dr. Parisian will also not be permitted to testify as to the 'knowledge, motivations, state of mind, or purposes' of Abbott, its employees, the FDA, or FDA officials.").

V. Dr. Parisian’s report consists of impermissible “narrative” testimony.

Regarding narrative testimony, Plaintiffs cite to prior rulings of this Court permitting what they characterize as similar testimony. Pl. Opp. at 7-9. Missing from Plaintiffs’ Opposition is *any* citation to Dr. Parisian’s reports, or deposition testimony, to explain why and how *her* testimony is admissible. *Id.* The Court is left only with Plaintiffs’ promise that Dr. Parisian will not embark on an impermissible narrative.

The absence of any support—by Plaintiffs, the proponent of Dr. Parisian’s testimony who bear the burden to establish admissibility—is particularly noticeable here, in light of the legion of courts excluding Dr. Parisian where she offered a “regurgitation of facts.” *See* Defs.’ Mem. at 12-14 (collecting cases excluding Dr. Parisian on these grounds).²

VI. Plaintiffs’ argument on “post-market vigilance” is not responsive to the pending motion and, in any event, Plaintiffs concede such testimony is irrelevant and will not be offered by Dr. Parisian.

Plaintiffs offer an argument in their Response regarding “Dr. Parisian’s opinion that Ethicon failed to comply with applicable post market vigilance.” Pl. Opp. at 9-10. It is unclear what Plaintiffs are referring to or how this is responsive to Ethicon’s motion. If Plaintiffs mean to challenge the argument that Dr. Parisian may not offer legal conclusions, they are incorrect as a matter of well-settled law. *See* Defs.’ Mem. at 11-12. In any event, Plaintiffs concede that such information is “admittedly irrelevant and will not be offered at trial.” Pl. Opp. at 9. Any such testimony should be excluded.

² Indeed, the state court testimony by Dr. Parisian attached to Plaintiffs’ Opposition at Ex. A illustrates this point. It consists of hours’ and hours’ worth of narrative testimony by Dr. Parisian. That testimony also, overwhelmingly, was about the FDA’s 510(k) clearance process, which this Court has excluded in prior mesh cases.

VII. Dr. Parisian is not qualified to opine on foreign regulatory matters; her testimony is not reliable; and the opinions would not be helpful to the jury.

Plaintiffs' Opposition offers precious little to conclude that Dr. Parisian's "considerable experience renders her qualified" to offer opinions about foreign regulatory matters. Pl. Opp. at 10. They simply state that Dr. Parisian will "only" opine on "global *regulatory standards*." *Id.* (emphasis in original). Plaintiffs then cite to a single paragraph from Dr. Parisian's report, which purportedly "explains in detail" her "unique qualifications to opine on foreign regulatory matters, including practical application of global industry standards:" (Pl. Opp. at 10):

18. Over the course of my career, I have been an integral member as a regulatory consultant for multiple companies and review teams, where we determined whether the products would be sufficient to meet FDA's regulatory requirements and global industry standards. As part of this analysis, I would consider whether additional studies/testing was required, and, if additional studies/testing was required, what types of studies/testing were needed. Additionally, I determined whether the proposed device label was adequate and all-encompassing according to the various industry and regulatory standards and my training and experience. For example, in my role as the Medical Officer in OHA, I was required to provide FDA's official comments and participate with various International and national industry groups to help develop industry standards' for medical devices. Since leaving the FDA there were many years when I continued to be a regulatory and medical expert on industry standard committees involved with design, development and critique of voluntary medical device industry standards. I have often been asked to evaluate the types of proposed testing/studies for a manufacturer as related to industry standards for manufacturing and clinical trials needed to obtain patient data and update labeling and marketing and training even when clinical studies were not required under FDA's guidelines to obtain 510(k) clearance. I have utilized clinical trials and studies (clinical data) to inform companies and physicians about the risk benefit ratio of a particular product or types of products, which assisted them in the creation of IFUs ,training and marketing materials, which had to be consistent with both the potential risks and benefits of a new device or product and FDA's intended use. I have presented on US medical devices to foreign regulatory agencies as well as foreign medical organizations as to how products were evaluated in the United States, the use of the product in patients, labeling requirements for the FDA, as- well as for helping industry obtain reimbursement from the foreign regulatory agency. I also had to have a working familiarity with United States and International standards and requirements to help a Sponsor harmonize its products for marketing both in and outside the United States.

Defs.’ Mot. at Exh. B: Parisian TVT-S Rep. at ¶18. A few nonspecific references to participation, presentations and/or “helping” are insufficient to deem Dr. Parisian qualified as an *expert* in foreign regulatory matters, and in any event this does not amount to the as-promised “detailed explanation of her methodology on this point.” Pl. Opp. at 10. Likewise, Plaintiffs’ casual statement, without any citation to the record for any support for *this* witness, that her testimony will be “helpful to the jury” is unavailing. Any testimony by Dr. Parisian regarding foreign regulatory matters should be excluded.

VIII. Dr. Parisian should not be permitted to testify about the adequacy of the warnings because Plaintiffs have failed to establish that she is qualified or that has employed a sufficient methodology.

Plaintiffs’ Opposition fails to establish that Dr. Parisian is qualified to opine on warnings in this case; it likewise fails to meet Plaintiffs’ burden to show that Dr. Parisian has employed a reliable methodology regarding product warnings. Perhaps most fundamentally, Plaintiffs mischaracterize Ethicon’s arguments and citations to the record. Plaintiffs claim that Ethicon’s argument “centers almost exclusively on her lack of involvement with the specific devices at issue . . .” and, further, that “[a]n expert’s failure to examine a particular source of information is not grounds for exclusion under *Daubert*” Pl. Opp. at 11, 15.

Plaintiffs’ argument sidesteps the actual arguments in Ethicon’s motion. It is not that Dr. Parisian is missing one small piece of an entire puzzle. Quite the contrary is true. As reiterated in the bullet-point list above, there are multiple reasons that, taken together, render her unqualified and without a reliable methodology.

Namely, it is not *only* that Dr. Parisian has no relevant medical experience with the conditions in issue; has never participated in studies regarding any mesh device; has never done any testing; and has never seen the products in issue. *See* Section III, *supra*; Def. Mem. at 6-9, 15-17. It is *also* that Dr. Parisian has no relevant knowledge as to the implanting physicians who

would receive the warnings in the IFU because she has never spoken to any such physician, read any such deposition, or conducted any survey to determine the surgeons would understand from their training and experience. *See* Def. Mem. at 15-16. It is *also* that Dr. Parisian freely admitted, at her deposition, that she does not know what a surgeon reading the IFU would know. *See id.* It is also that Dr. Parisian seeks to offer an *expert* opinion on warnings, yet testified that she does not know what the pertinent risks were at the pertinent point in time, nor has she identified what words needed to be deleted or added to make the warnings adequate. *See id.*³

Thus, Plaintiffs' effort—to cast Dr. Parisian in the same light as other experts who have been permitted to testify because they had “other ‘sufficient facts or data to support [his or] her opinion,’” Pl. Opp. at 12-13 (citing *Mathison v. Boston Scientific Corp.*)—falls short. Dr. Parisian has a litany of shortcomings particular to the warnings involved here, and these render her testimony inadmissible under *Daubert*.⁴

Plaintiffs' additional reference—five pages' worth (out of hours' worth) of testimony by Dr. Parisian in a prior mesh state court case—otherwise provides no support. Again, in that case,

³ Plaintiffs identify a sentence in Ethicon's memorandum that should have stated, as Dr. Parisian testified, that she had never drafted an adequate IFU or patient brochure. *See* Pl. Opp. at 17; Def. Mot. at Exh. E, at 71:2-5 (“Q: Have you written a draft IFU or patient brochure for TVT-Secur that is adequate in your opinion? A. No, I have not written a draft.”). Ethicon would note that Plaintiffs' Opposition cites to Dr. Parisian's Prolift+M testimony, which is not in issue here and the transcript accordingly was not attached to Ethicon's motion—only the TVT-Secur is at issue in Wave 2 for Dr. Parisian. *See* Pl. Opp. at 17 (citing Prolift + M testimony, where Dr. Parisian discussed that she was a consultant for Stanford University on a device for the brain to treat Alzheimer's, where she helped investigators in a clinical trial; the project did not take off and she does not know what happened to it; *see also id.* at 55 (discussing that she had not drafted a patient brochure from square one)).

⁴ Plaintiffs also make a passing reference to Dr. Parisian being qualified because she “incorporates a multitude of international standards, including GHTF standards, NICE recommendations, and the HAS standards.” Pl. Opp. at 6. Plaintiffs then summarily urge the Court to find Dr. Parisian qualified. *See id.* This cursory reference is unsupported by the record and fails to provide any support for admissibility of Dr. Parisian's opinions.

the judge acknowledged concerns about Dr. Parisian's proclivity to "go far afield;" the judge applied and permitted testimony on different standards than those allowed in this MDL; and the court nevertheless limited the scope of Dr. Parisian's labeling testimony. *See* Section I, *supra*.

In this case, Dr. Parisian does not have the fundamental understandings necessary to provide *expert* opinions on the warnings. Dr. Parisian cannot be permitted to tell a jury what should have been in the product warnings to make them accurate when she herself has no knowledge of what the risks actually were.

Dr. Parisian's failure to account for what the intended users of the products already know is critical and demands exclusion of her testimony. It is a well-known common law principle that there is no duty to warn of risks already known by the foreseeable user of the product. *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j.⁵ This also consistent with the FDA's regulations. *See* 21 C.F.R. §801.109(c) (manufacturer need not

⁵ *See also, e.g.*, 2-12 Frumer and Friedman, PRODUCTS LIABILITY §12.07[1][a] (2016); N.J. Stat. Ann. § 2A58C:4 (1987) ("[a]n adequate product warning or instruction is one that . . . communicates adequate information on the dangers and safe use of the product, . . . taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician"); Conn. Gen. Stat. § 52-572q (b)(2) (2008) (factor to be considered in determining whether warning required is "the ability of the product seller to anticipate that the expected product user would be aware of the product risk, and the nature of the potential harm"); Kan. Stat. Ann. § 60-3305 (2007) (no duty to warn about risks "which a reasonable user or consumer of the product, with the training, expertise, experience, education and any special knowledge the user or consumer did, should or was required to possess"); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (no duty to warn of characteristics "well known to the medical community"); *Guevara v. Dorsey Labs.*, 845 F.2d 364, 367 (1st Cir. 1988) (summary judgment for defendant based on "the general level of knowledge existent in the target [medical] community"); *Huskey v. Ethicon, Inc.*, No. 2:12-CV-05201, 2015 WL 4944339, at *7 (S.D. W. Va. Aug. 19, 2015) ("The medical device manufacturer, however, need not warn about 'risks already known to the medical community'" (Illinois law) (citation omitted); *Carlin v. Superior Court*, 920 P.2d 1347, 1354 (Cal. 1996) ("a pharmaceutical manufacturer may not be required to provide warning of a risk known to the medical community"); *Zachary v. Dow Corning Corp.*, 884 F. Supp. 1061, 1065 (M.D. La.1995) ("the duty to warn in the learned intermediary context requires an adequate warning of inherent dangers not within the knowledge of or obvious to the average learned intermediary").

warn of risks “commonly known to practitioners licensed by law to use the device”). This failure to account for intended users’ knowledge renders Dr. Parisian’s methodology flawed and unreliable. *See Calisi v. Abbott Labs*, 2013 U.S. Dist. LEXIS 139257, *26 (D. Mass. Sept. 27, 2013) (excluding regulatory expert’s opinion about sufficiency of warnings because “[w]ithout knowing the baseline of what information is needed, it is not possible to opine meaningfully on the information’s adequacy for [physicians]”). Further, her opinions are inconsistent with the legal standard to be applied by the jury, and therefore do not fit this case. *See In re Welding Fume Prods.*, 2005 WL 1868046, at *7 (N.D. Ohio Aug. 8, 2005) (excluding expert’s opinion regarding adequacy of the warning because the incorrect standard applied by the expert “does not necessarily translate to a legal warning requirement, nor does it necessarily imply liability”).

Dr. Parisian should be precluded from offering testimony about warnings, here, given her overall lack of qualifications and failure to employ a reliable methodology.

CONCLUSION

As set forth in Ethicon’s opening motion and memorandum in support and as discussed above, Dr. Parisian should be excluded from testifying in the three cases identified in Exhibit A to Ethicon’s motion. Ethicon prays for all other relief to which it is entitled.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones

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